negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, they may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the requirement in section 736B(d)(3) of the act.

II. Additional Information on PDUFA

There are several sources of information on FDA's Web site that may serve as useful resources for stakeholders participating in the periodic consultation meetings:

- Information on the April 2010 public meeting on PDUFA Reauthorization, the **Federal Register** notice announcing the meeting, and the transcript of the meeting are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm.* The slide presentations from the meeting can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0128.
- FDA created a webinar on the PDUFA program, drug development, and FDA's drug review in PDUFA IV. These presentations are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm207597.htm.*
- Key **Federal Register** documents, PDUFA-related guidances, legislation, performance reports, and financial reports and plans are posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm.*
- The Food and Drug Administration Amendments Act of 2007 (FDAAA)-specific information is available at: *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm*

III. Notification of Intent to Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding PDUFA Reauthorization, please provide notification by e-mail to *PDUFAReauthorization@fda.hhs.gov* by June 25, 2010. Your e-mail should contain complete contact information, including name, title, affiliation, address, e-mail address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: June 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13671 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0259]

Array-Based Cytogenetic Tests: Questions on Performance Evaluation, Result Reporting and Interpretation; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Array-Based Cytogenetic Tests: Questions on Performance Evaluation, Result Reporting and Interpretation. The purpose of the public meeting is to seek input on challenges related to performance evaluation, determination of clinical significance, result reporting, and interpretation for array-based cytogenetic tests.

Date and Time: The meeting will be held on June 30, 2010, from 1:30 p.m. to 5 p.m.

Location: The meeting will be held at Hyatt Regency Bethesda, 7400 Wisconsin Ave., 1 Bethesda Metro Center, Bethesda, MD.

Contact: Susan Monahan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20903, 301–796–5661, e-mail: *Susan.Monahan@fda.hhs.gov*; or Zivana Tezak, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5668, Silver Spring, MD 20903, 301–796–6206, e-mail: *Zivana.Tezak@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by June 21, 2010. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

If you wish to make an oral presentation during the open comment session at the meeting, you must indicate this at the time of registration. FDA has included general discussion topics and specific questions for comment in section III of this document, Topics for Input. You should also identify which discussion topic you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you need special accommodations due to a disability, please contact Susan Monahan or Zivana Tezak (see *Contact*) at least 7 days in advance.

Comments: FDA is holding this public meeting to obtain input on a number of questions regarding review and interpretation issues for array-based cytogenetic testing.

Regardless of attendance at the meeting, interested persons may submit either electronic or written comments on any discussion topic(s) to the open docket. The deadline for submitting comments to the docket is July 30, 2010. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section III of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Many human genetic disorders are a result of the gain or loss of human genetic material, which may manifest as congenital anomalies, dysmorphic features, developmental disabilities, etc. Traditionally, chromosomes were analyzed using a method called karyotyping. In addition, molecular methods such as fluorescence in situ hybridization (FISH) provide the information about chromosome abnormalities at specific loci. The recent

development of deoxyribonucleic acid (DNA) array methodologies, such as microarray-based comparative genomic hybridization (aCGH) and single-nucleotide polymorphism (SNP) arrays allow a high-resolution evaluation of DNA copy number alterations associated with chromosome abnormalities. Array-based cytogenetic testing is currently being implemented in the clinical setting as a method for detecting pathological genomic copy number changes.

FDA regulation and review of in vitro diagnostic devices has traditionally been a single marker-based, indication-specific process that ensures safety and effectiveness of the product. However, the results obtained from array-based cytogenetic tests are not necessarily predefined and may not be associated with known clinical syndromes. Evaluating complex devices such as array-based cytogenetic tests challenges the traditional method of FDA review.

II. Meeting Overview

During the meeting, FDA staff will present a brief background and overview of in vitro diagnostic (IVD) regulation. Specific questions related to review challenges for array-based cytogenetic tests are listed in section III of this document, Topics for Input. After the open comment session, the meeting will close with a round-table discussion between FDA staff and selected participants representing a range of constituencies. The participants in the round-table discussion will engage in a dialogue on discussion topics (see section III of this document), and provide closing thoughts. The participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to the round-table discussion.

In advance of the meeting, additional information, including a meeting agenda, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Topics for Input

FDA seeks input on the following issues:

1. Clinical significance

a. The resolution of array-based cytogenetic tests and the presence of copy number variations (CNVs) in the apparently healthy population poses challenges for result interpretation. What criteria should be used to determine the clinical significance of CNVs (e.g., when categorized as benign, pathogenic, or of unknown significance)?

b. Should there be different requirements implemented for interpreting the clinical significance of deletions vs. duplications vs. translocations?

2. Result reporting and interpretation

a. Should result output be limited to results associated with known syndromes that can be adequately validated clinically and analytically?

b. What criteria (e.g., minimum overlap, size, etc.) should be used to conclude findings are indicative of known syndrome?

c. Should the performing, ordering and/or result interpretation of these tests be limited to certain professionals (e.g., clinical cytogeneticists)?

d. How does FDA ensure that the results are interpreted correctly?

3. Additional and confirmatory testing

a. Should any array-based cytogenetic testing of an affected individual include testing of parents where possible?

b. Should a second followup test (e.g., FISH) be required for result confirmation prior to reporting array-based cytogenetic results?

4. Incidental findings

Laboratories are obliged to report clinically significant findings unrelated to the test order, when identified. How can the reporting of results for diseases or conditions outside of the indications for use be restricted?

5. Clinical evaluation for approval of array-based cytogenetic devices

a. Would validation of a group of CNVs associated with well-known syndromes be acceptable as a representation of all types of detectable CNVs?

b. If yes, then which syndromes should be included and how many CNVs would be a representative number?

c. What should be used as the reference genome?

d. What studies should be performed to understand clinical specificity?

6. Use of database(s) in result reporting

a. How can the accuracy of information used in the determination of results be assured?

i. Who should develop and maintain a curated database of known/probable CNV changes and benign findings in the population?

ii. FDA regulations require that all aspects of a test involved in result output are under design controls in accordance with the Quality System regulations. When implementing the database for result reporting, how can it be assured that the database is adequately maintained and meets appropriate quality standards?

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: June 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13768 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Planning Centers for Interdisciplinary Research in Benign Urology (IR–BU) (P20).

Date: July 9, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington, DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.